DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

950564

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE-01-05W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 15, 2004

Dr. Richard Hart
President / CEO
American Diagnostica, Inc.
500 West Avenue
Stamford, CT 06902-6360

Dear Dr. Hart:

We are writing to you because on August 2 through 5 and 10, 2004, the Food and Drug Administration (FDA) conducted an inspection of your Stamford, CT facility, which manufactures in-vitro diagnostic devices (IVDs), which are medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The inspection revealed that these devices are adulterated under section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements for medical devices set forth in the Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance and approve according to established procedures a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, your firm failed to validate the lyophilization process used in the manufacture of your IVD products. During the inspection you informed the Investigators that you had moved the lyophilizer [redacted] Since that time, no validation activities have been performed with respect to lyophilization conducted using this piece of equipment.

2. Failure of a formally designated complaint unit to maintain a record of investigation into a complaint involving the possible failure of a device to meet specifications, as required by 21 CFR 820.198. For example, your firm received a complaint [redacted] March 12, 2004, relating to tPA/PAI Depleted Plasma, # 273, lot [redacted] The complaint stated that the reading was too high. The record of investigation into this complaint omits information on the results of the investigation and any corrective action taken.

3. Failure to establish and maintain procedures for implementing corrective and preventive action, including requirements for implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5). For example, your firm received a complaint [redacted] on June 19, 2004 on your product, ESH 8, lot [redacted] This complaint noted that the product was not working on Western Blots, as specified in your labeling. Your investigation into the matter confirmed the nature of the complaint, yet no CAPA was initiated to correct the labeling.

4. Failure to conduct quality audits to assure that your firm's quality system is in compliance with the established quality system requirements and to determine the effectiveness of your firm's quality system, as required by 21 CFR 820.22.

Further, your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that there was a failure or refusal to furnish material or information required by or under section 519 of the Act, 21 U.S.C. 360i, respecting the device. You failed to report to FDA any correction or removal of a device to reduce a risk to health within 10 working days of initiating the correction or removal, as required by the correction and removal regulations (21 CFR part 806), promulgated under section 519(f)(1) of the Act, 21 U.S.C. § 360i(f)(1).Specifically:

In May 2003, your firm was notified of a potential manufacturing defect for your product, Simplify, D-dimer assay, product ID 800SF, [redacted] The foreign manufacturer indicated that there may be a problem with the foil pouch that contained the product cartridge. During the inspection, you indicated that a recall had been initiated for this product in May 2003. FDA was not notified of this product correction/removal.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and FDA regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Current Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at www.fda.gov/cderh/dsma/dsmastaf.html.

It is necessary to take action on this matter now. Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response or any questions you may have to Karen Archdeacon, Compliance officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. Her telephone number is (781) 596-7707.

Sincerely yours,

Gail T. Costello
District Director
New England District